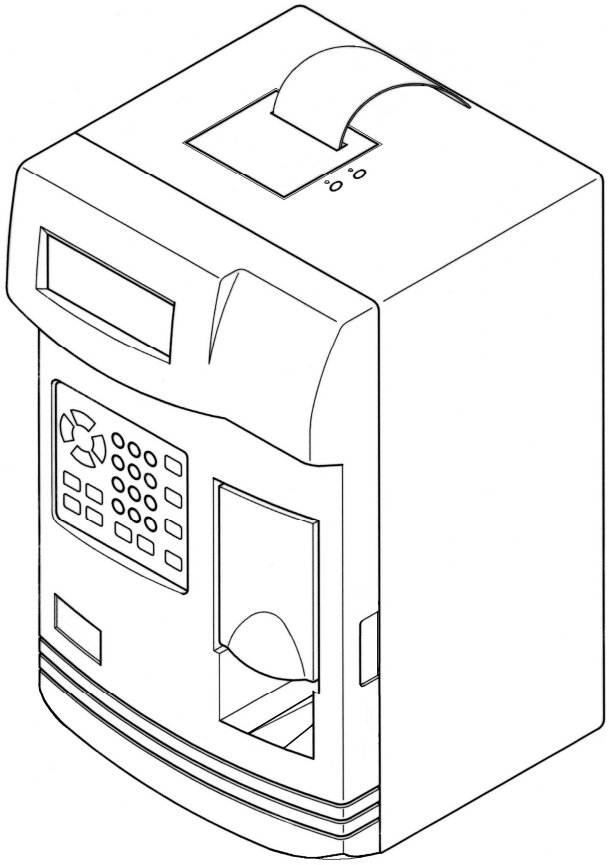
Biolyte 2000

Quick User Manual



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◆ Preface

Intended Use

The **Biolyte 2000** is intended for ***in vitro*** diagnostic use by healthcare professionals in the quantitative determination of sodium, potassium, chloride, or lithium (option) in whole blood, serum, and plasma; sodium, potassium, and chloride in whole blood, serum, plasma, urine and CSF. **All the data reported from the Biolyte 2000 are for clinical reference. If abnormal clinical data occur, further studies and evaluation of these data are suggested to ensure clinical safety.**

Intended Audience

The Biolyte 2000 Quick User Manual is written for healthcare professionals who operate the Biolyte 2000. Users do not need prior experience with BioCare products, but should have been trained on the instrument by BioCare's designated personnel.
This manual simply describes the Biolyte 2000 and explains how to test samples with them. If you need more detailed information, please refer to Biolyte 2000 reference manaul.

Technical Assistance

For technical assistance, call BioCare Corporation's Customer Service Center at +886-3-2616678.

◆ Description

Installing the Biolyte 2000

Users must complete the following steps to install the Biolyte 2000. Some procedures may not apply to all instruments.

- Unpacking the Biolyte 2000 and accessory boxes.
- Confirming voltage range.
- Assembling and installing electrodes.
- Installing the septum.
- Installing the probe.
- Installing the tubing.
- Installing the reagent pack.
- Powering on the instrument.
- Preparing the printer.
- Conditioning electrodes and flow path.
- Performing instrument calibration.

The Biolyte 2000 weighs approximately 26 lbs. (12 kg) (without reagent pack). BioCare recommends that at least 1 person help to remove the instrument from its shipping carton and place it on the counter. Complete the following steps to install and assemble the instrument:

Unpacking the Biolyte 2000 and Accessory Boxes

1. Inspect the boxes for any shipping damage. Contact BioCare if necessary.
2. Put the box facing up. Open the top lid of the carton box. Take out the accessory box.
3. Open the accessory box and check its contents with the enclosed packing list before proceeding with the installation. Contact BioCare if users are missing users' parts.
4. Remove the top foam end cap. Gently remove the Biolyte 2000 from the carton box and place it on the counter.
5. Remove the reference manual and the power cord from the carton box.

Confirming Voltage Range

6. The power input module permits the Biolyte 2000 to run at 0.6A/100-240VAC.
7. Confirm that the voltage of users' laboratory is in the range of Biolyte 2000's specification. Turn the instrument around in order to view the backside. The power-input module is located where the power cord connects to the Biolyte 2000.
8. Confirm the availability of appropriate fuse for the required voltage. See Table 1 below for the fuse that is required for the Biolyte 2000.

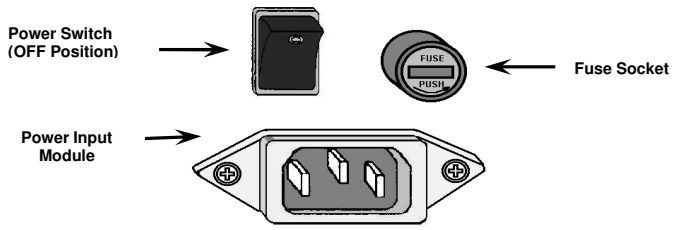


Figure1. Power Input Module and Fuse Socket.

Table 1 Fuse for Various Line Voltages

V	*A*	*Fuse Requirement*
100-240	0.6	2.0A SB (T2.0A/250V)

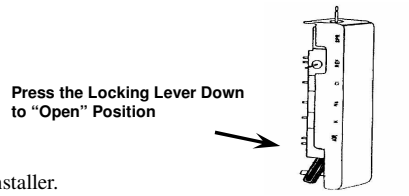


Figure2. "Open" Position.

Assembling and Installing Electrode

9. Remove the electrodes and electrode carrier from the packing material.
10. Place the electrode carrier on the table with the locking lever pointing towards the installer. Press the locking lever down to its "Open" position (see Figure 2).
11. Insert each electrode into the electrode carrier as follows:
    A. Insert the electrode with the pins facing up and to the left side of the electrode. Note that the gasket placement of each electrode (except for the spacer) will be towards the top.
    B. Align the lip of the electrode to the guide rails at the side of the electrode train. Slide in the electrodes from the bottom towards the top of the electrode train.
    C. Install the electrode in the following order: Spacer, Reference Electrode, Chloride Electrode or Lithium Electrode, Sodium Electrode, Potassium Electrode, and Air Detector (see Figure 3).
    D. The electrodes are keyed so users cannot install them upside down.

Note: Make sure there is a sealing gasket between each of the electrodes in the carrier.

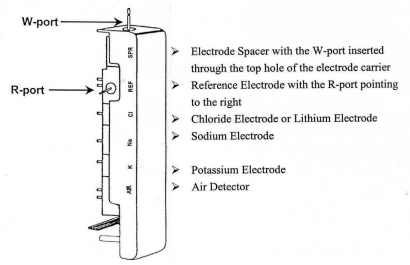

W-port
R-port
Electrode Spacer with the W-port inserted through the top hole of the electrode carrier
Reference Electrode with the R-port pointing to the right
Chloride Electrode or Lithium Electrode
Sodium Electrode
Potassium Electrode
Air Detector

Figure3. Electrode Carrier with Installed Electrode

12. Engage the locking lever at the bottom of the carrier to secure all the electrodes in the carrier. The lever should be in its "Closed" position.
13. Align the connector pins on the electrode and the electrode carrier with the receptacles on the instrument.
14. Gently push the electrode carrier into place on the Biolyte 2000, pressing from the bottom and the top simultaneously.

Installing the Septum

15. Remove a septum from the reagent pack.
16. Lift the sampler to the manual position and install the septum into the bayonet lock located on the under surface of the sampler. Turn the septum clockwise 1/4 turn to lock it in place.

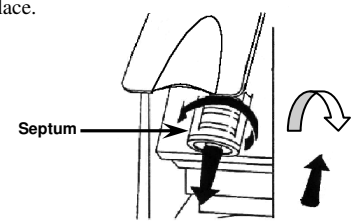


Figure4. Install the Septum.

Installing the Probe

17. Open the analyzer door.
18. Unscrew the locking screw from the top of the sampler arm.
19. Insert the long end of the probe through the sampler arm and into the septum.
20. Slip the locking screw over the short end of the probe. Finger tightens the locking screw onto the sampler arm.

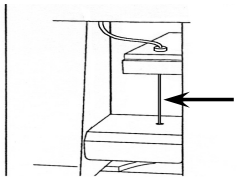


Figure5. Install the Probe.

Installing the Tubing

21. Connect 1 end of the S-line (Sample Tubing) to the down side of the electrode carrier and thread the other end to the probe.
22. Loosen the pump. Insert the W-line (Waste Tubing) into the pump. The yellow collar must be detained at the left pump bracket. Fasten the pump. Connect the W-line to the top of the electrode carrier. Thread the W-line into place inside of the waste valve. Attach the fitting on the reagent harness.
23. Connect the R-line (Reference Tubing) to the left-hand side of the electrode carrier. Thread the R-line into place inside of the reference valve. Attach the fitting on the reagent harness.
24. Connect the A-line (STD-A Tubing) and B-line (STD-B Tubing) to the septum. Attach the fitting on the reagent harness.

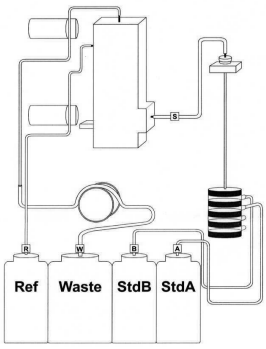


Figure6. Install tubing.

Installing the Reagent pack

25. Unscrew the bottle caps of all reagents and the waste bottle.
26. Place a reagent pack half-way onto the fluid deck.
27. Insert the tubing harness straws into the appropriate bottles.
28. Push the reagent pack all the way in.
29. Check all tubing connections. Incorrect installation may result in backward flow and contamination of reagent packs.
30. Plug the RMS into the RMS port (See Figure7 for the location of the RMS port).

Powering on the Instrument

31. Insert the female end of the power cord into the Power Input Module plug receptacle. Please position the equipment properly, to prevent that it is difficult to operate the disconnecting service. Plug the other end of the cord into a wall socket.
32. Switch the power button "ON". It is located on top of the Power Input Module. The instrument is now powered on.
33. The instrument screen should now display the system initialization procedure.

Preparing the Printer

34. Install the printer paper.

Conditioning Electrodes and Flow Path

35. Perform the conditioning procedure for the sodium electrode.
36. Perform the conditioning procedure for the flow path.

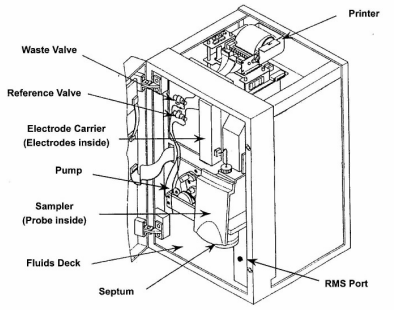
Performing Instrument Calibration

37. From the Menu Screen, press 6 to access the Maintenance Screen. Select the Prime option. Select the Full Prime option, then press Enter key to initiate a full prime of all fluids.
38. Press Calibrate key to initiate a manual calibration. Repeat procedure at least one more time.

Main Components

The Biolyte 2000's Main Components (Figure7) include tubing and flow controller to aspirate fluids, an electrode carrier to analyze samples and several communication devices to receive and display information. The Biolyte 2000 also includes a replaceable reagent pack that contains all of the reagents to calibrate the instrument and analyze samples.

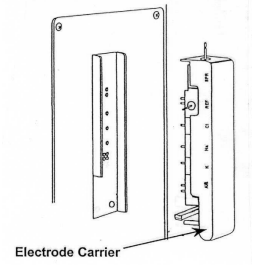
Figure7 Main Component.



Electrode Carrier

The electrode carrier (Figure8) houses the analytical components that measure analyte concentrations in a sample. It includes the measuring electrodes, a reference electrode, a spacer, and an air detector. Each measuring electrode quantities a specific analyte.

Figure8 Electrode Carrier



Measuring Electrodes

During an analysis or calibration, fluid fills the electrode carrier and each electrode generates an electrical potential (or current) in proportion to the amount of its specific analyte in the fluid. Then the microprocessor calculates the concentration of each analyte in the fluid, based on the output of each electrode.

Reference Electrode

The reference electrode supplies a continuous electrical potential in contrast to a measuring electrode. The reference electrode's potential varies with each particular sample. Because electrical potential can only be measured in comparison to a known voltage, the Biolyte 2000 uses constant voltage supplied by the reference electrode, to measure the potential produced by each measuring electrode.

Air Detector

The air detector is located below the potassium electrode and has 2 functions: it verifies the presence of air or fluid in the electrode train. The microcomputer monitors the air detector so that it knows when to stop the pump from aspirating a fluid once it fills the electrode train. When the air detector takes a reading during an analysis, it knows whether it is detecting air or fluid. The air detector is an optical sensor that can detect air and fluids.

Keypad

The keypad (Figure9) is located on the left, front side of the Biolyte 2000 and contains both numeric and function keys.

Figure9 Keypad

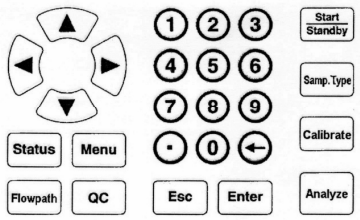


Table 2 The Function Keys

Key	Function
Analyze	Initiates a specimen analysis or restart an interrupted analysis.
Calibrate	Initiates a 2-point calibration.
←	Delete characters on an input screen.
Enter	A select highlighted number of data, initiates sequences, and selects options. The Enter key transfers data from the screen to the microcomputer.
Esc	Aborts procedures and calls up the previous screen. Accesses the Main Screen. Interrupts an analysis.
Flowpath	Begins and ends a flow path maintenance sequence.
Menu	Displays the Main Screen from the sensor Status Screen.
QC	Accesses QC functions.
Samp. Type	Displays the Sample Type Set Screen.
Status	Displays the Full Sensor Status Screen and the Biolyte 2000 Status Screen.

Start/Standby	Makes the screen of Biolyte into “Standby Mode”. Press again to return to Main Screen.

Liquid Crystal Display (LCD)

The Biolyte 2000 uses 40 characters * 4 lines LCD screen. The Biolyte 2000’s main screen is shown in Figure10.

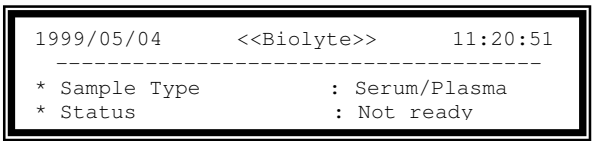


Figure 10 Main Screen

The main screen contains the following information: the currents date and time, sample type, and status.

Acceptable Samples

The following chart lists acceptable sample types for the different parameters measured:

PARAMETER	SPECIMEN MATRIX
Sodium	Serum, plasma, whole blood, or urine
Potassium	Serum, plasma, whole blood, or urine
Chloride	Serum, plasma, whole blood, urine or CSF
Lithium	Serum, plasma, whole blood

Sample Handling Requirement

Because the specimens have biohazard and infect, users have to wear glove during all analysis process. Proper sample handling is critical to ensure that values obtained accurately reflect the *in vivo* state. Ensure that all samples have been obtained and stored following consistent, clinically accepted protocols. The following is a discussion of general guidelines in reference to sample collection handling requirements for the Biolyte 2000.

The NCCLS Approved *Guideline on Procedures for the Handling and Processing of Blood Specimens* indicates that serum or plasma should be physically separated from contact with cells as soon as possible to a maximum time limit of 2 hours from the time of collection. It is also recommended that a contact time of less than 2 hours be established for serum or plasma sample intended for potassium analysis.

Reference Intervals

Each laboratory should establish and maintain its own reference intervals based on its patient population.

Table 3 Reference Intervals[1]

	Serum	Urine (24hr.)	Whole Blood	CSF
Sodium	136-146 mmol/L	60-220 mmol/day	136-146 mmol/L	
Potassium	3.5-5.0 mmol/L	1.0-10.0 mmol/day	3.5-5.0 mmol/L	
Chloride	98-106 mmol/L	60-200 mmol/day	98-106 mmol/L	118-132 mmol/L
Lithium	0.5-1.20 mmol/L			

Display Range for Analytes

The following display ranges are used by the Biolyte 2000 to check for result range errors (low or high), if the concentration of an analyte falls outside the range for a specimen sample type; the specimen cannot be tested for that analyte.

Table 4 Display Range by Sample Type

Analytes	Serum, Plasma, Whole Blood	CSF	Urine
Sodium	60-200 mmol/L	---	40-400 mmol/L
Potassium	1.0-10.0 mmol/L	---	3-300 mmol/L
Chloride	60-200 mmol/L	60-200 mmol/L	40-400 mmol/L
Lithium	0.1-5.0 mmol/L	---	---

◆ Set Up

Introduction

The Biolyte 2000's Set Up options let users define the instrument's operating parameters to accommodate users' laboratory's testing needs. To access the Set Up Screen (Figure11), from the Menu Screen (Figure11), input 1 and press Enter key.

```
<< SETUP >> Input No.? 1      10:06:12
1. Test select      2. Units setting
3. Resolution set   4. 2-Pt cal setup
5. Date/Time set    6. Results settings
```

Figure 11 Set Up Screen

Set Up Options in Menu

Selecting Electrodes

Use this function to turn "ON" or "OFF" each electrode. Figure12 shows the Test Select Screen.

1. The flowchart on the left side of this page is the step-by-step procedure for Selecting Electrodes.

```
<< TEST SELECT >>                11:20:51
1. Na+    : ON          2. K+  : ON
3. Cl-    : ON          4. Li+ : OFF
>>Press Enter key to change. (ON,OFF)
```

Figure12 Test Select Screen

2. Use ◄ ► ▲ ▼ keys to move the cursor, and press Enter key to turn "ON" or "OFF" the test electrode.
3. After setting the test electrode, press Esc key twice to return to the Menu Screen.

Selecting Units of Measurement

The Units Setting Option lets users select the units of measurement for the analysis report of each test. Figure13 shows the Units Setting Screen, which lists all of the system tests and the units of measurement that, users can select for each one.

1. The flowchart on the left side of this page is the step-by-step procedure for Selecting Units of Measurement.

```
<< UNITS SETTING >>                  08:30:32
1. Na+    : mmol/L        2. K+  : mmol/L
3. Cl-    : mmol/L        4. Li+ : mmol/L
>>Press Enter key to change. (mmol/L,mEq/L)
```

Figure13 Units Setting Screen

2. Use ◄ ► ▲ ▼ keys to move the cursor, and press Enter key to change the units of measurement.
3. After setting the units of measurement, press Esc key twice to return to the Menu Screen.

(Note: Only Na^+ and K^+ can be set to mmol/L or mEq/L.)

Setting Resolution Values

The Resolution Set Option lets users specify the number of decimal places that the Biolyte 2000 reports for sodium, potassium, chloride, and lithium results. Figure14 shows the Resolution Set Screen with the alternate resolution values.

1. The flowchart on the left side of this page is the step-by-step procedure for Setting Resolution Values.

```
<< RESOLUTION SET >>                    08:30:32
1. Na+    : 123         2. K+  : 12.3
3. Cl-    : 123         4. Li+ : 1.23
>>Press Enter key to change. (123,12.3)
```

Figure14 Resolution Set Screen

2. Use ◄ ► ▲ ▼ keys to move the cursor, and press Enter key to change the number of decimal places.
3. After setting the resolution values, press Esc key twice to return to the Menu Screen.

Table 5 Resolution Options for Analytes

	Resolution		
Analyte	***1 mmol/L***	***0.1 mmol/L***	***0.01 mmol/L***
Na^+	X	X	
K^+		X	X
Cl^-	X	X	
Li^+			X

Setting Two-point Calibration Interval

The 2-Pt Calibration Setup Option lets users specify the two-point calibration interval for Biolyte 2000. Figure15 shows the 2-Pt Calibration Setup Screen.

1. The flowchart on the left side of this page is the step-by-step procedure for setting two-point Calibration Interval.

```
<< 2-PT CALIBRATION SETUP >>    11:20:51
* Calibration interval: 2 hour

>>Range: 1 - 12 hour
```

Figure 15 2-Pt Calibration Setup Screen

2. Input the number 1~12, and press Enter key to set the two-point calibration interval.
3. After setting the two-point calibration interval, press Esc key twice to return to the Menu Screen.
4. If the input number is larger than 12, Biolyte 2000 will alarm, and return to the previous value.

Setting Date and Time

The Biolyte 2000 displays the date and time on each screen and on every printout. Users must enter the date and time when the instrument is first powered up; users can change it at any time. The internal clock has a battery that will maintain the correct date and time during long power outages. Figure 16 shows the Date/Time Set Screen.

Complete the following steps to change the date and time:
(Note: The Biolyte 2000 displays time in military units (i.e. 1:00PM. = 13:00))

1. The flowchart on the left side of this page is the step-by-step procedure for Setting Date and Time.

Figure 16 Date/Time Set Screen

On the Date/Time Set screen, a blinking cursor appears next to the first date field.

2. At the cursor, input a digit. Once input, cursor automatically jumps to the next digit.
3. Use [◄] [►] keys to move the position of cursor to the desired place, and use numerical key to input date or time. Then, at the end of the input, press [Esc] key twice to return to the Menu Screen.
4. When the input date or time is invalid, system will display a warning message "Invalid!" on line 1 of LCD (see Figure17).

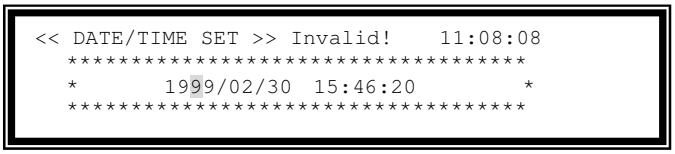


Figure 17 Date/Time Set Invalid Screen

5. Users must reset if "Invalid" appears.

Setting Results/Printer

The Results Set Option lets users define the reference values, panic values, and offsets values. Figure18 shows the Results Set Screen.

1. The flowchart on the left side of this page is the step-by-step procedure for accessing the Results Set Screen.

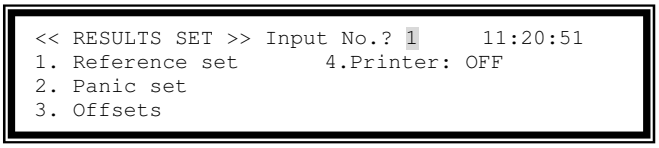


Figure 18 Results Set Screen

2. Input [1]~[4] and press [Enter] key to select function or press [Esc] key twice to return to the Menu Screen.
3. **The default value of printer is OFF**. Please input [4] and press [Enter] key to turn printer on.
4. Printer OFF function is designed for end-user who is able to analyze samples if the printer is defective. This is a temporary action; please replace related parts as necessary.

Setting Reference Values

The Reference Set Option lets users define the reference values of Biolyte 2000. Figure19 shows the Reference Set Screen.

1. The flowchart on the left side of this page is the step-by-step procedure for Setting Reference Values.

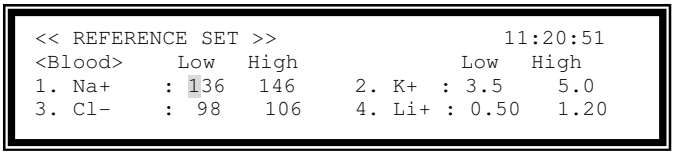


Figure 19 Reference Set Screen

Press [Samp.Type] key to change sample types. *(Note: <Blood> means serum/plasma or whole blood.)*

2. Use [◄] [►] [▲] [▼] keys to move the cursor.
3. Input the number (0.00~999), and press [Enter] key to set the reference values.
4. After setting the reference values, press [Esc] key 3 times to return to the Menu Screen.
5. If the input number is larger than 1000, Biolyte 2000 will alarm, and return to the previous value.
6. If the analysis data is out of the range of the reference values, Biolyte 2000 will automatically mark "<Ref" or ">Ref".
7. The resolution of the reference values depends on Resolution Set.

Setting Panic Values

The Panic Set Option lets users define the panic values of Biolyte 2000. Figure20 shows the Panic Set Screen.

1. The flowchart on the left side of this page is the step-by-step procedure for Setting Panic Values.

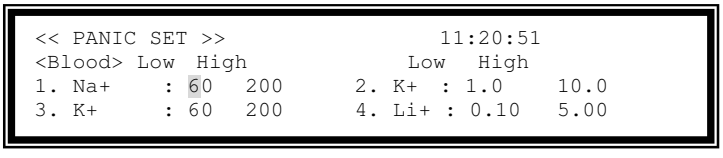


Figure 20 Panic Set Screen

Note: 1. <Blood> means serum/plasma or whole blood.
2. Only the panic values of serum/plasma and whole blood can be set.

2. Use [◄] [►] [▲] [▼] keys to move the cursor.

3. Input the number (0.00~999), and press Enter key to set the panic values.
4. After setting the panic values, press Esc key 3 times to return to the Menu Screen.
5. If the input number is larger than 1000, Biolyte 2000 will alarm, and return to the previous value.
6. If the analysis data is out of the range of panic values, Biolyte 2000 will automatically mark "<Pan" or ">Pan".
7. The Resolution of the panic values depends on Resolution Set.

Setting Offsets Values

The Offsets option lets users enter slope and intercept values for each analytical parameter so that users can correlate results from the Biolyte 2000 with other instruments in users' lab. Figure21 shows the Offsets Screen.

1. The flowchart on the left side of this page is the step-by-step procedure for Setting Offsets.

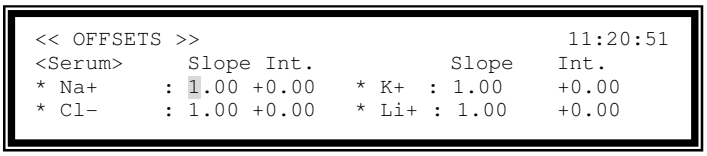


Figure 21 Offsets Screen

2. Press Samp. Type key to change sample types.
   (*Note: <Serum> indicates for both serum and plasma samples and <WB> indicates for whole blood samples.)*
3. Use ◄ ► ▲ ▼ keys to move the cursor.
4. Input the number of slope or intercept.
5. Press Enter key to change the sign (+/-) of intercept.
6. After setting the slope and intercept, press Esc key 3 times to return to the Menu Screen.
7. Table 6 shows the range of slope & intercept.

Table 6 Range of Slope and Intercept

	Slope	***Intercept***
Cl^-	0.8~1.2	±8.0
Na^+	0.7~1.3	±10.0
K^+	0.8~1.2	±0.5
Li^+	0.7~1.3	±1.0

Setting Operation Options

The Operation Options allow users to set the analysis result and alarm option. Figure 22 shows the Operation Screen.

1. The flowchart on the left side of this page is the step-by-step procedure for Setting Operation Options.

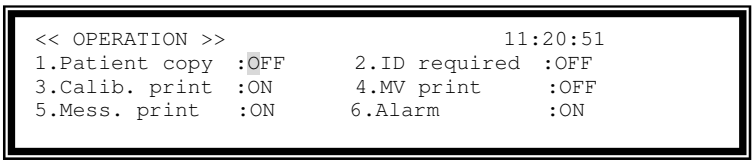


Figure 22 Operation Screen

2. Use ◄ ► ▲ ▼ keys to move the cursor, and press Enter key to switch the operation options "ON" or "OFF".
3. After setting the operation options, press Esc key to return to the Menu Screen.
4. Table 7 shows the description of the operation options.
5. Table 8 shows the description of the message.

Table 7 Description of the Operation Options

Option	***Default Set***	***Description***
Patient copy	OFF	Biolyte 2000 will print two analysis results if it were set "ON".
ID required	OFF	Users must input ID before analysis procedure if it were set "ON".
Calib. print	ON	Biolyte 2000 will print the calibration result after calibration if it were set "ON".
MV Print	OFF	Biolyte 2000 will print results of analysis & calibration including voltage of signals if it were set "ON".
Mess. Print	ON	1. Biolyte 2000 will print results including worry message if "occurred" if it were set "ON". 2. Table 2-3 shows the worrying messages.
Alarm	ON	System will alarm when error occurred if it were set "ON".

Table 8 Description of the Message

Message	***Description***
< Ref	Means assay concentration is less than reference low limit.
> Ref	Means assay concentration is greater than reference high limit.
< Pan	Means assay concentration is less than panic low limit.
> Pan	Means assay concentration is greater than panic high limit.
Drift	Means E_0 drift is greater than E_0 drift limit.
NC	Means the electrode isn't calibrated.

◆ Operation

Introduction

It includes two parts: **software description (software screen)** and **analysis operation procedures**. Most display screens and operation procedures are described in this chapter.

Main Screen

Push the Power Switch to "ON" position to turn the Biolyte 2000 on. Power Switch is located at the backside of the Biolyte 2000 (see Figure23). After system initiated, the screen will change to the Main Screen.

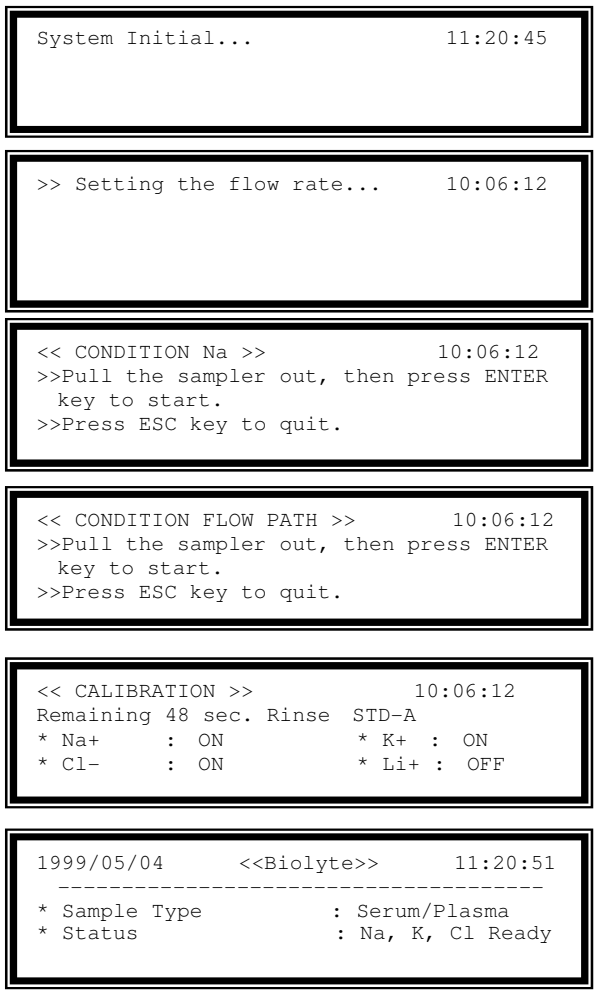


Figure23 From System Initial Screen to Main Screen

Table 9 describes the status in the Main Screen.

Table 9 Status Description in the Main Screen

Status	***Description***
"Parameter" ready	Indicates that the electrode(s) is ready and analysis can proceed.
Not ready	Must perform calibration before proceeding to analysis.
Flow path	Must perform Flow Path procedure before proceeding to other options.

In the Main Screen, users can use the waiting function keys as following:
Start/Standby Samp. Type Calibrate Analyze Menu QC Status Flowpath.

Start/Standby Function Key

Users can press Start/Standby key in the Main Screen. Figure24 shows the Standby Screen.

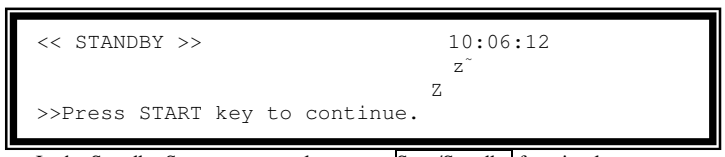


Figure24 Standby Screen

1. In the Standby Screen, users only can use Start/Standby function key.
2. Under the Standby Mode, during auto-calibration, no calibration is carried out, instead system will rinse STD-A for 5 seconds and REF for 2 seconds.
3. After pressing the Start/Standby key, system will run flush procedure, and then return to the Main Screen.

Note: After a power failure, when the electricity return, reload back to the previous standby or normal mode.

Samp. Type Function Key

Users can press Samp. Type key in the Main Screen. Figure25 shows the Sample Type Set Screen.

```
<< SAMPLE TYPE >> Input No.? 1 11:20:51
1. Serum/Plasma        2. Whole blood
3. Urine               4. CSF
>>Sample Type: Serum/Plasma
```

Figure25 Sample Type Set Screen

- ">>Sample Type: Serum/Plasma" means the selected sample type at present.
- Input 1~4 and press Enter key to change sample type, or press Esc key to return to the Main Screen.
- When sample type is changed, the calibration status of Biolyte 2000 will change to NC. Recalibrate must be done before proceeding to analysis procedure.
- When sample type change to urine, system will display the "HELP FOR URINE SAMPLE" screen for analyze urine sample analyses (Figure26)

```
<< HELP FOR URINE SAMPLE >>     11:20:51
1. Dilute one part urine sample with two
   parts diluent(Part. No.: 1030072).
2. Use diluted sample to run ANALYZE.
```

Figure26 Help for Urine Sample Screen

Calibrate Function Key

Users can press Calibrate key in the Main Screen. Figure27 shows 4 screens of the Calibration Screen.

```
<< CALIBRATION >>            10:06:12
Remaining  48sec. Rinse STD-A
* Na+     :  ON          * K+    :  ON
* Cl-     :  ON          * Li+   :  OFF
```

```
<< CALIBRATION >>              10:06:12
* Next auto-calibration time = 109 min.
* Na+ : 156.42 mV    * K+   : 12.54  mV
* Cl- : 123.45 mV    * AIR : 880.45 mV
```

Figure27 Calibration Screens

```
<< CALIBRATION >>              10:06:12
* Calibration flow rate       = 1.6 sec.
* Analysis flow rate          = 1.6 sec.
* Remaining reagent           = 100 %
```

```
<< CALIBRATION >>              10:06:12
          Na+     K+      Cl-     Li+
* Slope   50.00   50.00   -50.00   OFF
* Analysis test number: 1
```

System will start to calculate calibration time when Calibrate key has been pressed.

1. During calibration procedure, press Status key to switch between the four Calibration Screens.
2. At the end of calibration, system will set and calculate next auto-calibration time.
3. If calibration procedure is interrupted, system will rinse the flow path with STD-A and REF.
4. At the end of calibration, system will printout Figure28

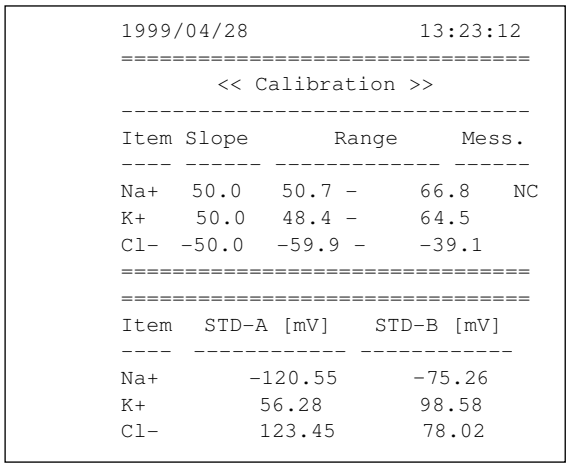


Figure28 Printout of Calibration

(1) NC: Means that the sensor is not calibrated.
(2) "MV Print" must be set "ON" in the Operation Option, for system to print this message.

Analyze Function Key

Users can press Analyze key in the Main Screen. Figure29A and Figure29B show the Sample Data Screen.

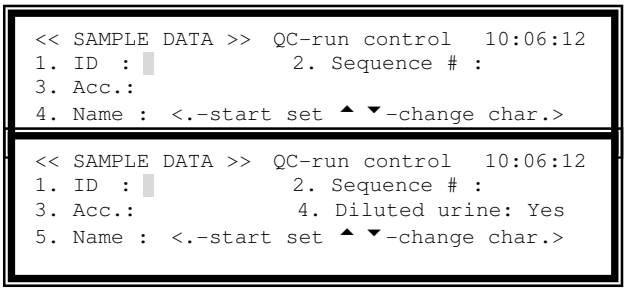


Figure29A. Sample Data Screen (for Serum/Plasma, Whole Blood and CSF)

Figure29B Sample Data Screen (for Urine)

1. System will clear error message of last analysis and begin calculating analysis time when users press Analyze key.
2. Calibration must be done before analysis procedure. If the selected electrode statuses are "NC", the screen will show Figure 30. Press any key to quit analysis procedure.

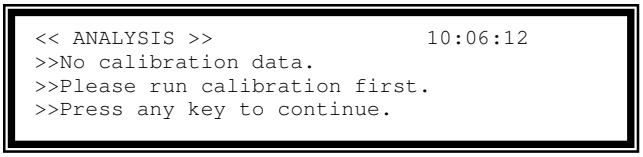


Figure30 NC Analysis Screen

3. Table 10 shows description options of the Sample Data Screen.

Table 10 Description Options of the Sample Data Screen

Option	*Description*
ID	10 characters (number or letter)
Sequence #	0-999 (auto count by system)
Acc. (Accession #)	0-9999999999
Diluted urine	Press Enter key to select "Yes" or "No".
Patient Name	20 characters (letter, [-], [.], [ ], [']) Press ◄ ► ▲ ▼ key to move cursor, then input information if desired.

◎ To input alphabets under the "ID" and "Patient Name" options, press . and ▲ ▼ key to select the desired alphabet.

4. If barcode reader has been installed, users can read bar code of ID or Acc. by barcode reader, when the cursor is at position of ID or Acc. When read data is out of range, system will alarm.
5. Press Analyze key to return to analysis procedure.
6. If operation option ID input is set "ON", ID must be input. If ID is not input when Analyze key is pressed, system will show Figure 31.

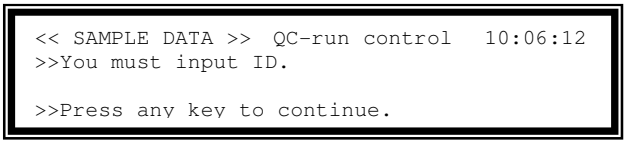


Figure31 Analysis Warning Screen

7. Figure32 shows 4 screens of the Analysis Screen.

```
<< ANALYSIS >>                10:06:12
Remaining  48sec.  Rinse  STD-A
* Na+      :  ON        * K+  : ON
* Cl-      :  ON        * Li+ : OFF
```

```
<< ANALYSIS >>                10:06:12
* Next auto-calibration time = 109 min.
* Na+      : -120.55 mV    * K+  :  12.54 mV
* Cl-      : 123.45 mV     * AIR : 880.45 mV
```

Figure32 Analysis Screen

```
<< ANALYSIS >>                10:06:12
* Calibration flow rate       = 1.6 sec.
* Analysis flow rate          = 1.6 sec.
* Remaining reagent           = 100 %
```

```
<< ANALYSIS >>                10:06:12
           Na+     K+      Cl-     Li+
* Slope    NC       50.00   -50.00   OFF
* Analysis test number : 1
```

8. During analysis procedure, press Status key to switch between the four Analysis Screens.
9. Once sample analysis is finished, the printer will automatically print the results. During printing, an Analysis Concentration Screen (Figure33) will appear. Once printing is finished, the system remains in the Analysis Concentration Screen for 5 seconds, or otherwise press any key to automatically return to the Analysis Screen.

```
<< ANALYSIS >>                10:06:12
  Item    conc.        Item    conc.
* Na+ :  NC           * K+  : 3.12  mmol/L
* Cl- : 100.2 mEq/L   * Li+ :  OFF
```

Figure33 Analysis Concentration Screen

- Unit and resolution depend on Set Up set
- OFF: Means that sensor is not being selected.

10. If the analysis procedure is interrupted, system will rinse the flow path with STD-A and REF.
11. At the end of analysis, system will print results as shown in Figure34.

Note: For QC analysis, press QC instead of Analyze key.

```
1999/04/28              13:23:12
================================
<< Analysis >>
SAMPLE ID   : A122113994
Access #    : 1221159940
Name        : S-M WU
Sequence #  : 1
Analyze Date: 1999/04/28
Analyze Time: 13:24:10
Sample Type : Serum/Plasma
--------------------------------
Item  Concentration    Message      <-- *(1)
---- --------------  -----------
Na+                     NC         <-- *(2)
K+         3.12 mmol/L
Cl-      100.2  mEq/L    Drift     <-- *(3)
================================
================================
Item    STD-A [mV]   Sample [mV]   <-- *(4)
----  ------------ ------------
Na+      -120.55       -75.26
K+         56.28        98.58
Cl-       123.45        78.02
================================
```

Figure34 Printout of Analysis

(1) "Message Print" must be set "ON" in the Operation Option, for system to print this message
(2) NC: Means that the sensor is not calibrated.
(3) Drift: Means that the voltage of STD-A taken during analysis is too large compared with the voltage of STD-A during calibration.
(4) "MV Print" must be set "ON" in the Operation Option, for system to print this message.

Status Function Key

The Status Screen can call up in any screen by pressing the Status key. Figure 35A, B, C shows the Status Screens.

1. Press Status key to change the Status Screens or press the Enter key to print all status information.
2. The Status Screen 1 (Figure 35A) shows the last-conducted calibration slopes of each sensor. The analysis test number will auto-count from 1 to 10,000.

```
<<STATUS>> Press ENTER to print. 10:06:12
           Na+      K+      Cl-      Li+
* Slope     NC     50.00   -50.00     OFF
* Analysis test number : 1
```

Figure35A. Status Screen 1

3. The Status Screen 2 (Figure35B) shows voltage values of each sensor that has been selected. All signals change per second.

```
<<STATUS>> Press ENTER to print. 10:06:12
* Na  : -120.55 mV     * K+  : 12.54   mV
* Cl- : 123.45 mV     * AIR : 880.45 mV
* Next auto-calibration time = 109 min.
```

Figure35B Status Screen 2

4. [illegible] procedure. All signals change per second.

```
<<STATUS>> Press ENTER to print. 10:06:12
* Calibration flow rate       = 1.6 sec.
* Analysis flow rate          = 1.6 sec.
* Remaining reagent           = 100 %
```

Figure35C Status Screen 3

5. Press Esc key to quit the Status Screen.

Flowpath Function Key

Press Flowpath key in the Main Screen. System will prime air into the analyzer until S-line, electrode train, and W-line are empty. Once empty, screen will display to the Flowpath Screen 1 (Figure36).

```
<< FLOWPATH >>                    11:20:51


>> Press FLOWPATH key to continue.
```

Figure36 Flowpath Screen 1

Either press Flowpath key again while in the Flowpath Screen 1 to prime all fluids into the tubing and return to the Main Screen (Figure 3-1), or, system will automatically prime all fluids after one hour of idling. Before priming all fluids into the tubing, system will beep 10 times (once per second) and display the Flowpath Screen 2 (Figure37). To stay at flowpath mode (or empty tubing), press ESC key during these 10 seconds.

```
<< FLOWPATH >>                    11:20:51

>> Press ESC key to stay at flowpath mode.
>> Press FLOWPATH key to continue.
```

Figure37 Flowpath Screen 2

Menu Function Key

Press Menu key in the Main Screen to enter Menu Screen. Figure38 shows the Menu Screen.

```
<< MENU >> Input No. ? 1          11:20:51
1. Setup              2. Operation
3. Data               4. Software version
5. Diagnostic         6. Maintenance
```

Figure38 Menu Screen

Input 1~6 and press Enter key to select function, or press Esc to return to the Main Screen.

Software Version

Diagnostic When Menu key was pressed in the Main Screen, system will enter the Menu Screen. Input 4 and press Enter key in the Menu Screen to enter the Software Version Screen. Figure 39 shows the Software Version Screen.

```
<< SOFTWARE VERSION >>          10:06:12
* Main program version    : B4.2A
* Test program version    : 3.3
```

Figure39 Software Version Screen

Biolyte 2000 Operation

This prologue contains shortcut instructions for running samples.

The Biolyte 2000 is a sophisticated instrument with many operating functions and convenient user features. This chapter explains in detail how to operate the Biolyte 2000. However, the Biolyte 2000 is also designed to accommodate users' need to run analyses quickly and simply without using all of the offered functions.

The following operation shortcuts allow users to analyze samples quickly without altering the instrument's set-up parameters.

Shortcut Procedures

The shortcut procedures are as shown on Figure40.

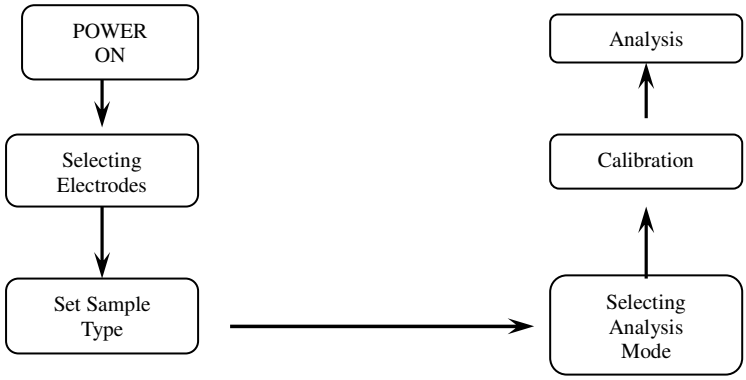


Figure40. Shortcut Procedures

Note: The Shortcut Procedures are for reference use only.
For more detailed information, please refer to the respective sections in this Reference Manual.

Power On

See **Powering on the Instrument** (Description, Figure1).

Selecting Electrodes

See **Selecting Electrodes** (Set Up, Figure12).

Set Sample Type

See Samp. Type **Function key** (Set Up, Figure25).

Selecting Analysis Modes

There are 2 analysis modes build in: Manual Mode and Semi-Auto Mode. User can position the arm straight to operate Semi-Auto Mode; lift up the arm to operate Manual Mode. The instrument has auto-sensor to distinguish the 2 modes automatically. (Figure 41A, 41B)

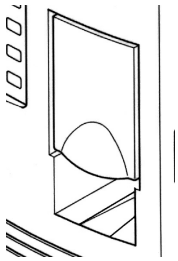


Figure41A Semi-Auto Mode

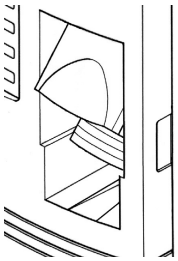


Figure41B Manual Mode

Note: Place the sample cup carefully to avoid any possible spills when using the Semi-Auto Mode.

Calibration

Press Calibrate key in the Main Screen to run calibration procedures.
There are two modes of calibration build in Biolyte 2000, Manual Calibration and Auto-calibration.

Manual Calibration

To initiate a manual calibration on the Biolyte 2000, press Calibrate key in the Main Screen.

Auto-Calibration

The Biolyte 2000 automatically initiates a calibration sequence 30 minutes after POWER ON and approximately every 2 hours thereafter, or 2 hours after the last manual calibration. To set two-point calibration interval, see **Setting Two-point Calibration Interval**.

◆ Maintenance

Introduction

Maintenance includes both daily and periodic maintenance procedures, as well as component replacement, non-routine maintenance and instrument shutdown/start up procedures.

The daily maintenance procedures should be performed before operating the instrument for the first time each day. The periodic maintenance procedures should be also performed according to users' scheduled timetables.

Maintenance Function

Biolyte 2000's maintenance functions shall be operated as described below.

Input 6 and press Enter key in the Menu Screen to enter the Maintenance Screen. Figure42 shows the Maintenance Screen.

```
<< MAINTENANCE >> Input No.?1     10:06:12
1. Condition         2. Clean flow path
3. Reagent info      4. Prime
5. Probe adjustment  6. Cal. pump frequency
```

Figure42 Maintenance Screen

Input 1~6 and press Enter key to select function or press Esc key to return to the Menu Screen.Table 11 shows the description of Maintenance Options.

Table 11. Description of Maintenance Options.

Option	*Description*
Condition	Running procedures for conditioning sodium electrode and flow path.
Clean flow path	Running procedures for cleaning flow path.
Reagent info	Showing the information of the reagent pack.
Prime	Running procedures for priming the selected solution or air.
Probe adjustment	Adjusting the probe position.
Cal. pump frequency	Calibrating pump frequency.

Daily Maintenance

The following maintenance procedures must be performed before users use Biolyte 2000 for the first time each day:

- Check the reagent pack level.
- Clean the sample inlet port.
- Condition Na electrode.
- Condition the flow path with serum.
- Check the slope and flow time.

Note: 1. BioCare recommends conditioning Na electrode and flow path before daily operation. Users must calibrate the instrument if electrode conditioning has just been performed.

2. All fluids in tubing are infectious, thus, must be handled with care! Wear gloves if necessary!

Perform the following steps to complete the daily maintenance procedures.

Checking the Reagent Pack Level

Press Status key repeatedly until the Status Screen 2 appeared (Figure35B). This screen shows the amount of the most consumed fluid that is left in the reagent pack. When it shows that the reagent pack is empty, replace the reagent pack according to the instructions that appear later.

Cleaning the Sample Inlet Port

1. Pull the sampler up to the manual position.
2. Clean the sample inlet port with a cotton swab moistened with deionized water.
   Note: If whole blood is analyzed frequently, clean the sample inlet port more often.

Conditioning Na Electrode

Press Menu key and input 6. Input 1 and press Enter key to select function to do conditioning Na electrode.

Conditioning the Flow Path with Serum

Press Menu key and input 6. Input 1 and press Enter key to select function to do the flow path with serum.

Checking Slope & Flow Time

Calibrate the instrument if electrode conditioning has just been performed. Calibration is initiated by pressing Calibrate key.

Checking the Electrode Slope

Press Status key repeatedly until the Status Screen 3 (Figure35C) appears. This screen displays the slope of the last calibration.

Checking the Flow Time

Flow time measures the time it takes for fluid to travel from the tip of the probe to the air detector.

Press Status key repeatedly until the Status Screen 2 (Figure35B) appears. This screen displays the flow times during the last calibration and analysis cycles, as well as their acceptable ranges.

Periodic Maintenance

Periodic maintenance procedures must be performed according to users' scheduled timetables to assure optimal instrument performance. Unless otherwise indicated, the flow path maintenance cycle must be initiated before the start of any maintenance procedures.

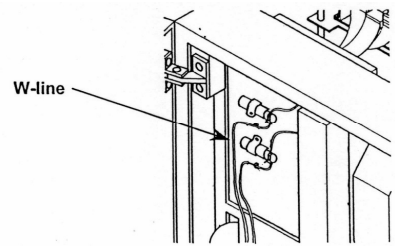
The flow path maintenance cycle purges the flow path of fluid and holds the instrument in an idle state while it is being serviced.

Flow Path Maintenance Cycle

To initiate the Flow Path Maintenance Cycle, press the Flowpath key once in the Main Screen. Or users can use Prime function and select "AIR" to empty flow path.

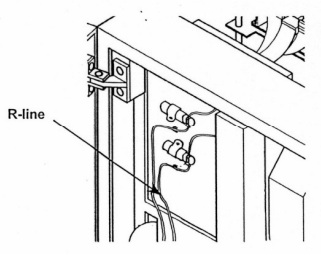
Replacing the W-line

Figure43 shows the location of the W-line.



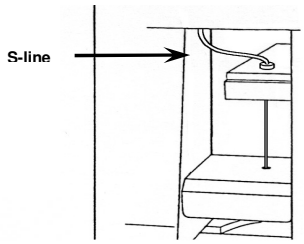
Replacing the R-line

Figure44 shows the location of the R-line



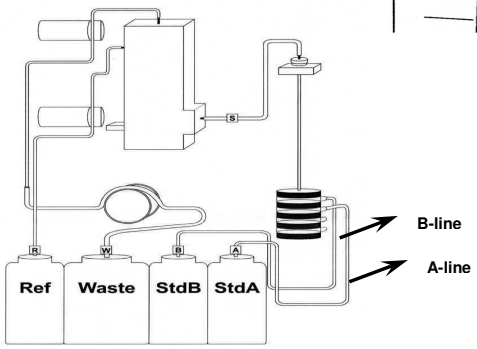
Replacing the S-line

Figure45 shows the location of the S-line



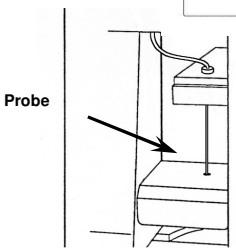
Replacing the A-line/B-line

Figure46 shows the location of the A-line and B-line



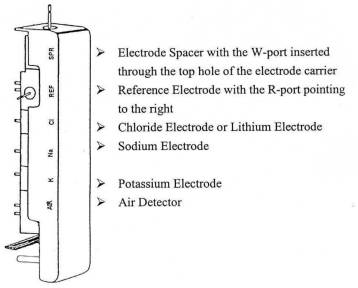
Replacing the Probe

Figure47 shows the location of Probe



Replacing the Electrodes

Figure48 shows the Electrode Carrier


Electrode Spacer with the W-port inserted through the top hole of the electrode carrier
Reference Electrode with the R-port pointing to the right
Chloride Electrode or Lithium Electrode
Sodium Electrode
Potassium Electrode
Air Detector

Non-routine Maintenance

Non-routine maintenance procedures are performed in response to trends in instrument operation that may generate error codes if left uncorrected, or as corrective actions in response to inappropriate or incorrect procedures.

Cleaning the Sample Inlet Port

See **Cleaning the Sample Inlet Port** in the earlier section.

Cleaning the Probe

The probe cleaning procedure is recommended when a gradual increase in flow times is observed. This cycle takes place with the sampler in the manual position. During the probe cleaning cycle, Cleaning Solution is aspirated from a sample cup into the electrode carrier. At the end of the cycle, the Cleaning Solution flushes into the waste bottle.
Complete the following steps to clean the probe:

1. Pull the sampler up to the manual position.
2. Fill the sample cup with 1ml of **CLEANING SOLUTION** (Part. No.: 1030012).
3. See **Clean Flow Path** in the earlier section of this chapter for details.
4. Recondition the flow path with serum (see Daily Maintenance Procedures), and recalibrate before proceeding to control and specimen assays.

Replacing the Reagent Pack

Replace the reagent pack and septum when the reagent pack has expired or is empty.

Note: 1. All fluids in tubing are infectious, thus, must be handled with care! Wear gloves if necessary!
2. Septum must be replaced together with the reagent pack.

Replacing the reagent pack and RMS

1. When the reagent pack has expired or is empty, system will show Figure49A and start emptying all standard solutions.

```
<< CHANGE REAGENT PACK >>       10:06:12
* Reagent pack has expired!
>> Emptying all standard solutions...
>> Press ESC key to quit.
```

Figure49A Change Reagent Pack Screen 1

2. After emptying all standard solutions, system will show Figure49B.

```
<< CHANGE REAGENT PACK >>       10:06:12
* Reagent pack has expired!
>> Please disconnect tubing (A, B, R),
   then press ENTER key to empty tubing.
```

Figure49B Change Reagent Pack Screen 2

3. Open the analyzer door.
4. Remove A, B, and R straws from their reagent bottles in the reagent pack. **Leave the W-line in the waste bottle**. Wipe each straw dry as it is lifted out of the bottles to prevent cross contamination. Leave A, B and R straws exposed to the air.
5. Press Enter key to empty tubing and system will show Figure49C.

```
<< CHANGE REAGENT PACK >>       10:06:12
* Reagent pack has expired!
>> Emptying tubing...
>> Press ESC key to quit.
```

Figure49C Change Reagent Pack Screen 3

6. After emptying all tubing, system will show Figure49D.

```
<< CHANGE REAGENT PACK >>       10:06:12
* Reagent pack has expired!
>> Please replace a new reagent pack,
   then press CALIBRATE key to start.
```

Figure49D Change Reagent Pack Screen 4

7. Remove the W-straw from the waste bottle. Wipe it dry with a tissue.
8. Turn off the power, then remove the old reagent pack and the old RMS.
9. Place the new reagent pack onto the fluids deck and plug the new RMS into the RMS port.

Replacing the septum

10. Disconnect the A-line and B-line from the old septum.
11. Turn the septum counterclockwise 1/4-turn, and remove it from the sampler (as shown in Figure50, left).
12. Discard the old septum.
13. Slide the new septum over the probe and turn it clockwise 1/4-turn to lock it into place (as shown in Figure50, right).
14. Connect the A-line and B-line to the new septum.
15. Insert the tubing harness straws into the appropriate bottles of the reagent pack.

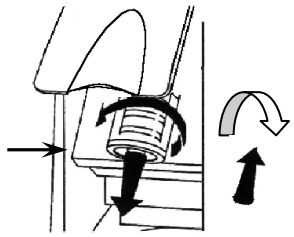


Figure50 Replacing the Septum

16. Press Calibrate key to start full priming and system will show Figure49E.

```
<< CHANGE REAGENT PACK >>       10:06:12
* New reagent pack
>> Full priming...
```

Figure49E. Change Reagent Pack Screen 5

17. After full priming, system will do auto-calibration.
18. Close the analyzer door.

Installation of Thermal Paper

This section does not only explain installation of thermal paper but also explain the replacement of thermal paper. Users can install/replace thermal paper according to the following procedures.

1. Open the printer cover.
2. Gently remove the old roll of paper.
3. Install a new roll of paper into the chamber.
4. Insert the tip of the thermal paper into the paper-inlet of the printer.
5. Press the ON LINE key on the top of the Biolyte 2000 once to turn off the ON LINE light indicator, then press the Feed key several times until the tip of the paper roll goes out through the outlet.
6. Pull the paper and center it.
7. Press the ON LINE key once to turn on the ON LINE light indicator.
8. Close the printer cover.

If the printer fails to print after a new roll of paper is installed, investigate the following causes:

- If the loose end feeds from the top of the roll, the roll of paper is installed upside down. Remove the roll, turn it around, and install it so the loose end feeds from the bottom of the roll.
- The printer paper is jammed. Check that the part number of the paper (Part. No.: 5020097) is correct for the Biolyte 2000's printer.
- After installing the thermal paper, check the ON LINE light indicator. If the ON LINE light indicator is off, press the ON LINE key once to turn on the ON LINE light indicator.

If the above-mentioned are checked and none of them is the cause of the printer failure, power off the Biolyte 2000 and try power on again.

Shutdown

Use the following shutdown procedures to prevent salt buildup in the flow path when the Biolyte 2000 is turned off or unplugged.

Note: All fluids in tubing are infectious. Thus, they must be handled with care! Wear gloves if necessary!

1. Open the analyzer door.
2. Remove A, B, and R straws from their reagent bottles in the reagent pack. **Leave the W-tubing in the waste container**. Wipe each straw dry as it is lifted out of the bottles to prevent cross contamination.
3. Leave A, B and R straws exposed to the air.
4. From the Menu Screen, press 6 to access the Maintenance Screen.
5. Select the Prime function. Then select the Full Prime option.
6. Press Enter key to purge fluids from all the tubes.
7. At the conclusion of the full prime cycle, immerse the ends of A, B, and R straws into a beaker of deionized water.
8. Press Enter key to fill the tubes with deionized water.
9. At the conclusion of the prime cycle, remove the straws from the beaker of water and leave them exposed to air.
10. Perform 2 full prime cycles with air to purge all water from the tubing.
11. At the conclusion of the second full prime cycle, remove the W straw from the waste bottle and wipe the straw.
12. If the reagent pack has a reasonable of reagent left, tape the holes on top of the bottles or cover them with parafilm to prevent evaporation of the fluids.
13. Release the collars of the W-line from the pump bracket.
14. Close the analyzer door.
15. Switch the power button OFF and unplug the Biolyte 2000.

◆ Troubleshooting

Introduction

It describes troubleshooting procedure for the Biolyte 2000 and provides instructions on how to use error codes and the Diagnostics Screen.

Troubleshooting Theory

The most efficient troubleshooting procedures focus on the simplest and fastest way to resolve error codes. Since most error codes are due to flow problem in the Biolyte 2000's flow path, it is logical to investigate flow problems first. It is helpful while troubleshooting to view the system as a whole and to consider how the flow path components interact to transport fluids throughout the Biolyte 2000. When multiple error codes occur, resolve the flow problems before troubleshooting the remaining error codes. In most cases, the accompanying errors are resolved along with the flow problems. Error codes that remain unresolved after flow problem has been corrected must be investigated individually.

Do not replace any flow path components until you resolved the flow problems, unless instructed to do so during the flow path check.

Troubleshooting Procedure

The recommended troubleshooting procedure consists of a series of steps that are designed to resolve a malfunction in the most direct and logical way. The following approach is used:

1. Eliminate obvious causes.
2. Troubleshooting individual error codes and groups of error codes by first eliminating flow problems. Then resolve any remaining error codes.

Proceed as follows to troubleshoot malfunction:

1. First eliminate all obvious problems that may have caused the malfunction.
   a. Investigate and correct, if necessary, the following possibilities:
      - Unplugged electrode
      - Disconnected tubing or septum
      - Empty reagent pack
      - Incorrectly connected reagent pack
   b. Perform a calibration to determine if all calibration errors have disappeared.
   c. If the calibration errors have disappeared, perform an analysis to determine if the analysis errors have also been resolved.
   d. If resolved, the troubleshooting procedure is now completed. If either calibration or analysis errors codes persist, proceed to Step 2 to continue.

2. Troubleshoot individual error codes. Refer to numerical list of error codes in Error Codes Table (see Biolyte 2000 Reference Manual). If a flow problem is suspected, you will be instructed to perform the flow path check at appropriate time. Special emphasis will be given to flow path components that are the most likely cause of the flow problem. Refer to flow path check later in this chapter for detailed instruction on how to perform this procedure.

After the corrective action in each step has been completed, perform a calibration or analysis or both to determine if the errors have been resolved.

If the proceeding troubleshooting procedure failed to resolve the Biolyte 2000's malfunction, call BioCare Customer Service Center.

Indicator of Flow Related Problem

The Biolyte 2000 monitors flow during every calibration and analysis cycle and provides the following useful flow indicators:

- Flow times
- Air and fluid readings

These flow indicators can help you to determine if a problem is flow related.

Flow Times

Press Status key repeatedly to view the last calibration and analysis flow rate.
A calibration or analysis flow time of zero indicates that no calibration or analysis has been performed since the instrument was powered down; therefore, data is unavailable.

Air and Fluid Readings

Press Menu key in the Main Screen. System will enter the Menu Screen. Input 5 and press Enter key to run diagnostic procedures. Then press 3 and press Enter key in the Diagnostic Screen to access the Air Detector Test function.

Flow Path Check

For troubleshooting purposes, the flow path has been divided into the following 6 sections:

1. W-line Check
2. S-line/Electrode Carrier Check
3. Probe Check
4. A-line & B-line Check
5. R-line Check
6. Septum Check

If you have determined the exact location of a flow problem, troubleshoot only that section of the flow path in which the problem originates.

If you have been unable to locate the source of the problem, troubleshoot the flow path in the recommended order to avoid duplicating steps. Investigate and correct each section completely before proceeding to the next one. Discontinue the flow path check as soon as the flow problem has been eliminated.

◆ Warranty of Products

The Products manufactured by BioCare Corporation (hereinafter called "BioCare") are warranted against defects in materials and workmanship prior their expiration date. The Instrument of Products is covered by a Warranty Period of 12 months warranty from the date of delivery. BioCare's liability under this warranty is limited, at the option of BioCare, for repair or replacement of the product. Item expendable through normal use is not covered by this warranty. All warranty repair or replacement of parts shall be limited to instrument malfunction, which, in the sole opinion of BioCare, is due or traceable to defects in the original materials or workmanship. All obligations of BioCare under this warranty shall cease in the event of abuse, accident, alteration, misuse, or neglect of the Products. In warranty repair or replacement, all parts are warranted for only the remaining unexpired portion of the original Warranty Period, applicable to the repaired or replaced parts. After expiration of the applicable Warranty Period, the customer will be charged at the current prices for parts, labor and transportation.

Reasonable care must be used to avoid hazards to the Products. BioCare expressly disclaims responsibility for loss or damage caused by the use of its ways other than in accordance with proper operating procedures.

EXCEPT AS STATED HEREIN, BioCare, MAKES NO WARRANTY, EXPRESSED OR IMPLIED OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE. Statements made by any person, including representatives of BioCare, which are inconsistent or in conflict with the terms of this warranty shall not be binding upon BioCare unless specified in writing and approved by BioCare.

All claims under this warranty must be made promptly after the occurrence of circumstances giving rise thereto, and must be received by BioCare or its authorized representative within fifteen (15) days after the instrument malfunction. Such claims should include the Products serial number, the date of purchase, and a full description of the circumstances giving rise to the claim. Before any Products are returned for repair and/or adjustment, written authorization from BioCare or its authorized representative for the return and instruction as to how and where these Products should be returned, must be obtained. Any Products returned to BioCare for examination shall be sent freight prepaid via the means of transportation indicated as acceptable to BioCare.

BioCare reserves the right to reject any warranty claim not promptly reported and any warranty claim on any item that has been altered or has been returned by non-acceptable means of transportation. When any product is returned for examination and/or inspection, or for any other reason, the customer shall be responsible for all damage resulting from improper packing or handling, and for loss in transit, notwithstanding any defector nonconformity in the product. In all cases, BioCare has the sole responsibility for determining the cause and nature of the failure; BioCare's determination with regard thereto shall be final.

If it has been found that the Products has been returned without cause and is still serviceable, the customer will be notified and the Products returned at its expense; in addition, a charge for testing and examination may be made to the Products so returned.

BioCare reserves the right to change, alter, modify or improve any of its Products without any obligation to make corresponding changes to any Products previously sold or shipped.

WHEN ENCOUNTERING ANY QUESTION ARISING FROM DIFFERENT LANGUAGE VERSIONS, THE ENGLISH VERSION WILL BE THE PRINCIPAL REFERENCE. IF YOU NEED MORE DETAILED INFORMATION, PLEASE REFER TO BIOLYTE 2000 REFERENCE MANAUL.

ALL THE DATA REPORTED FROM BIOLYTE ARE FOR CLINICAL REFERENCE, IF ABNORMAL CLINICAL DATA OCCUR, THE USERS ARE SUGGESTED TO TAKE FURTHER STUDIES AND EVALUATION OF THESE DATA TO ENSURE CLINICAL SAFETY.

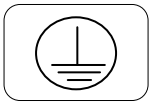
Assistance from this warranty is available through BioCare Corporation's Customer Service Center during normal business hours, Monday through Friday.

Customer Service Center
BioCare Corporation
Tel: +886-3-2616678
Fax: +886-3-2616679
E-mail: service@biocare.com.tw

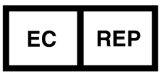
Warning Messages

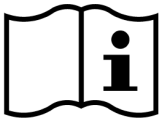
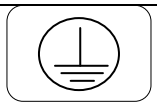
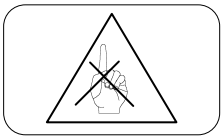
1. The Biolyte 2000 is for indoor use only.
2. Do not use the Biolyte 2000 in a manner not specified by BioCare Corporation.
3. Do not use the Biolyte 2000 with flammable substances.
4. The Biolyte 2000 should not be mounted on a surface of flammable material.
5. Take any possible hazards of explosion, implosion or release of toxic or flammable gases arising from the materials being heated away from the Biolyte 2000.
6. Use only a fuse and a power supply cord with the same type and rating as specified in the Appendix II.
7. User has the responsibility for carrying out appropriate decontamination (eg. scrubbing with 75% alcohol) if hazardous material is spilt on or inside the Biolyte 2000. To prevent shock hazard, disconnect power supply before cleaning of the unit.
8. Before using any cleaning or decontamination method except those recommended by BioCare Corporation, users should check with BioCare Corporation that the proposed method will not damage the Biolyte 2000.
9. Do not use the service program, which is for service engineers only.
10. When the Biolyte 2000 alarms or there is any error message shown, stop operating and check.
11. The electromagnetic environment should be evaluated prior to operation of the device.
12. Use of this instrument in a dry environment and don't use this instrument in close proximity to sources of strong electromagnetic radiation as these may interfere with the proper operation.
13. User's should ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended.
14. This equipment complies with the emission and immunity requirements described in this part of the EN 61326 series.

Description of IEC Letter Symbols

Symbol	Description	Symbol	Description
V	Voltage	|	Power On
~	Alternating Current	O	Power Off
A	Current		
	Protective Conductor Terminal		Attention, Consult Accompanying Documents

Labels on the Biolyte 2000

	For In Vitro Diagnostic Use K diagnostickému použití in vitro Für die In-vitro-Diagnostik Για In Vitro Διαγνωστική Χρήση Per uso diagnostico in vitro Pour le Diagnostic In Vitro
	European Conformity Evropská shody European Conformity Ευρωπαϊκή Συμμόρφωση Conformità europea Conformité européenne
	Manufactured by Vyrobené Hergestellt durch Κατασκευάζεται από Prodotto da Fait par
	Authorized Representative Oprávněný zástupce Authorized Representative Εντολοδόχος Rappresentante autorizzato Représentant autorisé
	Catalog Number Katalogové číslo Katalog-Zahl Αριθμός καταλόγου Numero di catalogo Catalog Number
	Lot Number Číslo šarže Lot-Nr Αριθμός παρτίδας Numero di lotto Numéro de lot
	Use by (YYYY-MM-DD) Použití (RRRR-MM-DD) Verwendung von (JJJJ-MM-DD) Χρήση από (EEEE-MM-HH) Uso da parte di (AAAA-MM-DD) L'utilisation de (AAAA-MM-JJ)
	Temperature Limit Mezní teplota Temperaturgrenze Θερμοκρασία Όριο Temperatura limite Limite de température

	Consult Instructions for Use Konzultovat Návod k použití Consult Instructions for Use Συμβουλευτείτε τις οδηγίες χρήσης Consultare le istruzioni per l'uso Consulter les instructions d'utilisation
	Biological Risks Biologická rizika Biologische Risiken Βιολογικοί κίνδυνοι Rischi biologici Risques biologiques
	Grounding Uzemnění Erdung Γείωση Messa a terra Grounding
	Peristaltic Pump Warning Peristaltická čerpadla Upozornění Schlauchpumpe Warnung Περισταλτικές Pump Προειδοποίηση Pompa peristaltica Warning Pompe péristaltique Avertissement
FUSE : T2 H250	Fuse Specification Pojistka Fuse Specification Fuse Προδιαγραφές Fusibile Specification Fuse Spécification